

Applicant: William Galbraith
Application No.: 10/804,592
Amendment to Office Action dated February 1, 2006
Office Action mailed November 1, 2005
Docket No.: P-6007/1 (102-585)
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REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested.

This Amendment is being filed in response to an Office Action which was issued on November 11, 2005. It is respectfully submitted that the present Amendment is timely submitted.

Claims 1-6, 24-31, and 50-51 are pending and under examination in the application. By this Amendment, new claims 50 and 51 have been added.

For the record, Applicant has noted errors in the published copy of this application (U.S. Patent Application No. 2005/0037331 A1, published February 17, 2005). Specifically, the chemical structure shown in paragraph [0028] incorrectly contains two boron atoms (indicated by the letter "B"), whereas it should instead contain two sulfur atoms (indicated by the letter "S"). The chemical structure originally submitted by Applicant correctly depicts bromosulfophthalein (hereinafter "BSP") with sulfur atoms. It also has been noted that the two sodium ions ("Na") in the structure incorrectly include negative charges. These atoms in fact include positive charges. The inclusion of incorrect charges is clearly a typographical error. Through this amendment, a substitute chemical structure is submitted which includes the correct information.

The Examiner rejected claims 1-6 and 24-27 under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 5,919,708 (hereinafter, "Sundrehagen"). This rejection is respectfully traversed.

Sundrehagen is directed to an assay for glycated blood proteins. The assay evaluates the level of protein glycation to determine a person's control of glucose concentration averaged over

a period of time. (column 1, lines 6-7; column 1, lines 20-32) As set forth at column 2, line 45-column 3, line 4, the Sundrehagen method includes, *inter alia*, separating glycated blood protein and corresponding non-glycated blood protein from a sample; contacting the sample with a first signal forming agent; and, optionally, contacting the sample with a second signal forming agent. As set forth at column 4, lines 14-20, the "protein separating step does not require the separation of the total amount of glycated protein and non-glycated protein present in the sample. It is sufficient for only a proportion of both the glycated and non-glycated fractions to be separated as long as the method is appropriately calibrated." Thus, an amount of the protein must be separated from the sample sufficient to evaluate the level of glycation.

Sundrehagen discloses various agents for achieving separation. With reference to column 11, lines 9-65, various precipitating agents are disclosed for separating the target protein from a sample. Bromosulphophthalein-glutathione is disclosed herein as an agent for use in the separating step. (column 11, lines 46-54). Specifically, bromosulphophthalein-glutathione is disclosed as an immobilized ligand.

Separately, BSP is disclosed at column 8, lines 5-6 as being an example of an organic dye which is usable as a second signal forming agent. (see, e.g. column 8, line 36 ("Other dyes which may be used as the second signal forming agent . . .")). The BSP is clearly used for a different purpose than the bromosulphophthalein-glutathione. Significantly, there is no disclosure or suggestion in Sundrehagen to have the second signal forming agents immobilized or attached to a support surface, much less to have BSP, in particular, immobilized or attached to a support surface. (see, column 4, lines 30-34, "Consequently, there is no need for the first signal-forming agent to be immobilised since it need not be used as part of a separation system, and indeed it is preferred that it is not immobilised.").

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Claim 1 of the present application calls for an apparatus including "an insoluble support having a ligand attached thereto", wherein said ligand comprises BSP or a salt of BSP or ester of BSP. In contrast, Sundrehagen does not disclose or suggest having BSP attached to an insoluble support. Rather, Sundrehagen makes a distinction between bromosulphophthalein-glutathione and BSP and discloses only immobilizing the former, not the latter. Moreover, there is no suggestion to modify Sundrehagen to have the BSP immobilized. As pointed out above, Sundrehagen includes an indication that the signal-forming agents are not to be immobilized. It is respectfully submitted that claim 1, along with dependent claims 2-6, are patentable over Sundrehagen.

Claim 24 is an independent claim which includes similar limitations to claim 1. For the reasons discussed above, it is respectfully submitted that claim 24, along with dependent claims 25-27, are patentable over Sundrehagen.

The Examiner rejected claims 24 and 27-31 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pub. No. 2002/0127739 (hereinafter, "Pieper") in view of Sundrehagen. The Examiner admitted that "Pieper et al. fail to teach a ligand of bromosulphophthalein" and relied on Sundrehagen for allegedly overcoming this deficiency.

In response, Applicant notes that Sundrehagen does not disclose the use of BSP as recited in claim 24, contrary to the Examiner's assertion. Rather, as noted above, Sundrehagen discloses the use of BSP in which the BSP is not attached to an insoluble support. The hypothetical combination of Pieper and Sundrehagen would use Pieper's method with BSP dissolved in a homogeneous solution. Accordingly, the hypothetical combination of Pieper and Sundrehagen does not teach each and every element of claims 24 and 27-31. It is respectfully submitted that claims 24 and 27-31 are patentable over Pieper and Sundrehagen, each taken alone or in combination.

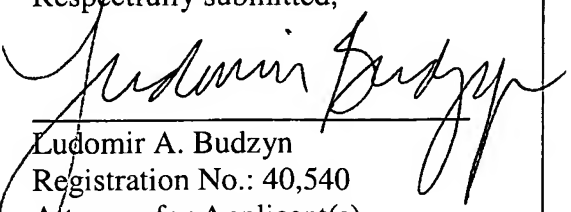
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New claims 50 and 51 have been added herein which respectively depend from claims 1 and 24. Both claims recite "said ligand is attached to said insoluble support via an epoxy linkage." It is believed that these claims provide an additional basis for patentability beyond that discussed above.

The Examiner maintained the double patenting rejection under 35 U.S.C. §101, in view of claims 1-6 and 24-31 of copending application No. 10/922,560. As indicated in the last response, Applicant intends on canceling claims 1-6 and 24-31 from copending application No. 10/922,560.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicant's attorney at the number listed below.

Respectfully submitted,



Ludomir A. Budzyn
Registration No.: 40,540
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700